

Guidance For Industry

INTERPRETATION OF ON-FARM FEED MANUFACTURING AND MIXING OPERATIONS

DRAFT GUIDANCE

This guidance document addresses the requirements for livestock producers who mix feed for their own ruminant animals and might be considered as “on-farm feed manufacturing and mixing operations” under 21 CFR 589.2000, Animal Proteins Prohibited from Use in Ruminant Feed.

This guidance represents current thinking and does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative approaches may be used if they satisfy applicable requirements.

The comment period for this draft guidance will begin on the day the Notice of Availability of the guidance publishes in the Federal Register. The Federal Register notice will state the length of the comment period. Comments and suggestions regarding the document should be submitted to Docket No. 98D-0727 after the notice publishes. For questions regarding this draft document, contact Gloria Dunnava, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-594-1726 E-mail: gdunnava@bangate.fda.gov.

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Draft Guidance

Interpretation of "On-farm Feed Manufacturing and Mixing Operations" in 21 CFR 589.2000

Introduction

Since FDA published 21 CFR 589.2000 (the BSE feed regulation),¹ the Center for Veterinary Medicine (CVM) has been asked whether ruminant producers who mix Total Mixed Rations (TMRs) are "feed manufacturers" under the rule. A very high percentage of dairy farms in the U.S. use TMR mixers, and most beef cattle feedlot operations have similar equipment.

This question raises the issue of whether these operations are "on-farm feed manufacturing and mixing operations" under the rule. If they are, the ruminant producers are "feed manufacturers" as defined by section 589.2000(a)(4) and are subject to different requirements under the rule than ruminant producers who are not feed manufacturers. Applicable portions of sections 589.2000(d), (e) and (f) apply to the former, subsection (f) applies to the latter. CVM has provided additional guidance in Guidance for Industry 69, "Small Entities Compliance Guide for Feeders of Ruminant Animals With On-Farm Mixing Operations," and Guidance for Industry 70, "Small Entities Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations."

This guidance document provides CVM's interpretation of the term "on-farm feed manufacturing and mixing operations" as it applies to producers who mix TMRs. CVM's interpretation is that the term does not apply to producers who mix TMRs but do not otherwise manufacture feed. These producers are not "feed manufacturers" under the rule. Subsection (f) and Guidance for Industry 70 apply to them, and they are required (among other things) to keep invoices and labeling for all animal protein products received. The Center's rationale is set forth below.

Discussion

In TMR systems, the nutrient components (forages, grains, and protein, mineral

¹ 62 Fed. Reg. 30936 (June 5, 1997). The purpose of the regulation is to prevent the establishment and amplification of bovine spongiform encephalopathy (BSE) in the United States, by prohibiting the feeding of certain mammalian protein to ruminant animals. The rule places labeling, recordkeeping and other requirements on several industry sectors, including feed manufacturers and ruminant feeders.

and vitamin supplements) of the animal's diet are grown locally or purchased from outside sources, and then mixed together on a daily basis at the feeding site. The goal is to produce a ration that, in each bite the animal takes, is nutritionally complete and balanced. The mixing equipment is usually a horizontal mixer that may be stationary, portable or self-propelled.

Ruminant producers with on-farm feed manufacturing and mixing operations are "feed manufacturers" under the rule. They are not required to keep invoices and labeling for all animal protein products received. CVM's intention when drafting the regulation was to include in the definition of "feed manufacturers" those relatively large integrated operations that have feed manufacturing equipment similar to a commercial feed manufacturer. Those operations typically manufacture feed and feed ingredients, but also mix feed for contract growers, for animals under their immediate control, or both.

By contrast, CVM's interpretation is that ruminant producers who prepare complete feed for their own animals using only the TMR system do not manufacture but only mix feed. Therefore, we conclude that these producers are not feed manufacturers under the rule because they only mix feed, but do not have feed manufacturing and mixing operations.

In interpreting the term "on-farm feed manufacturing and mixing operations," two issues are of particular concern to CVM:

- o The importance of having most ruminant feeders document **all animal protein products** they receive. Section 589.2000(f) requires ruminant producers to retain invoices and labels for all feeds received containing animal protein, whether or not the protein includes prohibited material. However, CVM's interpretation is that ruminant feeders with on-farm feed manufacturing and mixing operations are not required to keep invoices and labels for all animal protein-containing products received (except for any complete feed that the feeder might receive).² If "on-farm feed manufacturing and mixing operations" includes those that only mix TMRs, a high percentage of dairy farms and beef cattle feedlots will not be required to keep such invoices and labels. The purpose of the requirement is to provide a "safety net," to allow traceback from farms to suppliers to insure that product without the cautionary statement is properly labeled. If the requirement does not apply to producers with only TMR operations, traceback from

² CVM applied this interpretation in FDA Guidance for Industry 69. The basis for this interpretation is that the sections of the rule that are applicable to feed manufacturers ((d) and (e)) require feed manufacturers to keep only records of prohibited material; the Food, Drug and Cosmetic Act's general labeling requirements do not require labeling for feed manufactured on the farm; and the normal business practice of providing an invoice (a practice that the regulation relies on) does not apply to feed manufactured on the farm.

a significant proportion of producers would not be possible.

o The possible need for separation or cleanout for TMR operations. Although the practice is believed to be limited, it is possible that producers could use the same TMR equipment to mix feed for nonruminants (containing prohibited material) and for ruminants. If these producers are not defined as feed manufacturers under the regulation, they would not be directly subject to the requirements in section 21 CFR 589.2000(e) that are designed to prevent commingling or cross contamination of prohibited and nonprohibited material. CVM believes, however, that failure to prevent commingling or cross contamination in such a scenario could result in feed that is adulterated under the general adulteration provision of the Act. Therefore, the FDA would have regulatory authority to control such practice even if subsection (e) does not apply.

Guidance

After considering carefully the purpose of the regulation and the need to protect the public health, the Center provides the following guidance:

o Ruminant feeders will not be considered to be “feed manufacturers” for purposes of 21 CFR 589.2000 if they mix TMRs for their own animals and do not manufacture feed. These feeders are required, among other things, to retain invoices and labels for all feed ingredients received (such as protein supplements) that contain animal protein, whether or not the protein contains prohibited material. Additional guidance is in Guidance for Industry 70.

o Ruminant feeders who manufacture and mix feed for their animals, contract growers or both, will be considered “feed manufacturers” for purposes of the regulation. Section 589.2000 (d), (e) and (f) will apply to such operations as appropriate. Additional guidance is in Guidance for Industry 69.